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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------------|---------------------|------------------|
| 09/632,074 | 08/02/2000 | Geoffrey Charles Nicholson | DAVI103.001AUS | 9705 |
| 20995 | 7590 | 02/14/2005 | EXAMINER | |
| KNOBBE MARTENS OLSON & BEAR LLP | | | SAOUD, CHRISTINE J | |
| 2040 MAIN STREET | | | ART UNIT | |
| FOURTEENTH FLOOR | | | PAPER NUMBER | |
| IRVINE, CA 92614 | | | 1647 | |

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|--------------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/632,074 | NICHOLSON, GEOFFREY CHARLES | |
| | Examiner | Art Unit | |
| | Christine J. Saoud | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) 10, 13-16 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 17-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim 1 has been amended in the response filed 06 December 2004. Claims 1-10 and 13-19 are pending in the instant application. Claims 10, 13-16 and 19 stand withdrawn from consideration as being drawn to a nonelected invention. The election was made without traverse in the response filed 14 October 2003.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 06 December 2004 have been fully considered but they are not deemed to be persuasive.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on 03 August 1999. It is noted, however, that applicant has not filed a certified copy of the Australian application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "modulating bone resorption", and the claim also recites "wherein said modulation is a reduction" which is the narrower statement of the range/limitation.

The claim could be amended to recite "A method of reducing bone resorption ..." or "a method of inhibiting bone resorption", which would obviate the rejection.

Claim Rejections - 35 USC § 102

Claims 1-9 and 17-18 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ke et al. (U.S. Pat. No. 6,352,970) for the reasons of record in the previous Office action.

Applicant argues at page 7 of the response that "Ke et al. does not anticipate the claimed invention because Ke et al. does not teach each and every claim element because Ke et al. does not teach the use of Leptin to inhibit bone resorption" (emphasis omitted). This argument is not persuasive because Ke et al. teach a method of augmenting bone mass and preventing bone loss comprising administration of lepin. The method of Ke et al. comprises the administration of leptin; the amounts taught by Ke et al. encompass the amounts the instant specification indicates would be effective and sufficient to achieve the desired effect; and the patient population to which Ke et al. is administering the leptin is substantially the same as that of the instant claims. Therefore, even though Ke et al. do not disclose the biological activity of inhibiting bone resorption, this effect and outcome would be inherent to practicing the method of Ke et al., absent evidence to the contrary.

MPEP 2111.02 indicates "[I]f the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)". The instant claims appear to follow the same fact pattern, therefore, the preamble recited intended use is not considered a limitation of the claimed invention. Ke et al. meets the limitations of the claims and the desired result to be achieved would

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be inherent to the administration of the leptin by the method of Ke et al., absent evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 1-9 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. for the reasons of record in the previous Office action.

Applicant argues at page 7 of the response that "[t]he Examiner alleges that 'one of ordinary skill in the art would be motivated to administer leptin in order to stimulate bone resorption'" (emphasis omitted). However, the Applicant is incorrect in quoting the Examiner; no where in the previous Office action could this statement be found. At page 5 of the previous Office action it was stated "[o]ne of ordinary skill in the art would have been motivated to administer leptin to an individual with a bone resorption condition, such as osteoporosis, because treatment of such conditions with an agent that stimulates bone formation would be beneficial to the patient".

Applicant's reliance on the preamble of the claim is noted, but this argument is not persuasive for the reasons provided above; namely, that in the instant claim, the preamble is not given weight as a limitation of the claim. A method of treating patients in need of bone formation encompasses the same patient population of those patients in need of inhibition of bone resorption; the method requires the administration of leptin, which is taught in the prior art and administration to humans is obvious for the reasons of record (not traversed by applicant). Finally, the desired outcome of the claimed

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invention would be met inherently by practicing the method which is obvious in view of Liu et al., absent evidence to the contrary.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mtr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**CHRISTINE J. SAUD
PRIMARY EXAMINER**

Christine J. Saud